EXHIBIT C

GRINSPOON DECLARATION

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OAKLAND CANNABIS BUYERS' COOPERATIVE
AND JEFFREY JONES

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES,

Defendants.

AND RELATED ACTIONS.

No. 98-0088 CRB

DECLARATION OF LESTER GRINSPOON, M.D., IN SUPPORT OF DEFENDANTS' MOTION TO DISSOLVE AND OPPOSITION TO MOTION FOR SUMMARY JUDGMENT/PERMANENT INJUNCTION

Date: March 22, 2002
Time: 10:00 a.m.
Honorable Charles R. Breyer

I, LESTER GRINSPOON, M.D., declare:

1. I am an Associate Professor of Psychiatry, at Harvard Medical School in Boston, Massachusetts, where I have taught for more than 35 years. I am also Editor of The Harvard Mental Health Letter. My area of research is psychoactive drugs. I am particularly interested in the medicinal properties of cannabis. If called as a witness, I could and would testify competently to the facts set forth below. I have attached a copy of my *Curriculum Vitae* as Exhibit A. For the Court's convenience, where appropriate I have provided footnotes referencing the sources upon which I have relied.

2. I received a bachelor's degree in 1951 from Tufts College. I received a doctorate in 1955 from Harvard Medical School. I subsequently completed an internship in Medicine at Beth Israel Hospital in Boston, Massachusetts (1955-1956), and a residency in psychiatry at Massachusetts Mental Health Center (1958-1961). I received further training as a field instructor for the National Cancer Institute in Los Angeles, California (1956-1958).

3. Since joining the Harvard Medical School faculty in 1973, I have held numerous positions, including Associate Clinical Professor, Assistant Clinical Professor, and Senior Psychiatrist for the Massachusetts Mental Health Center. My other research and teaching appointments include, Assistant in Medicine for University of Southern California School of Medicine (1956-1958), Director of the Clinical Research Center for Massachusetts Mental Health Center (1961-1968), Consultant in Psychiatry and Research for Boston State Hospital (1963-1970) and an Examiner for the American Board of Psychiatry and Neurology (1969-present). I have also held several positions for the American Psychiatric Association such as Vice-Chairperson (1975-1977) and Chairperson for the Council on Research (1977-1979), Vice-Chairperson (1979-1980) and Chairperson for Scientific Program Committee (1980-1984).

4. I serve on several professional and community boards. These include many years as a member of the Beneficial Plant Research Association (1980-1984), the Drug Policy Foundation (1987-present), Physicians for Human Rights (1986-present), the Drug Research Group (1995-present),

and Scientific and Policy Advisors of the American Council on Science and Health (1997 - present). I recently served as Chairperson for the Board of Directors for the National Organization for the Reform of Marihuana Laws (1993-1995). I was also a faculty member for the Zinberg Center for Addiction Studies in Cambridge, Massachusetts (1993-1996). I am currently on several Editorial Boards, including editor for the Harvard Mental Health Letter (1984-present), the Journal of Social Pharmacology (1985-present), and Addiction Research (1991-present).

5. I have testified before the National Marijuana Commission Subcommittee of the Senate Small Business Committee in 1972, the House Select Committee on Narcotics in 1977, 1979 and 1989, the Controlled Substances Advisory Committee, the Drug Abuse Research Advisory Committee in 1978, the Senate Judiciary Committee in 1980, and the House Judiciary Committee, Sub-Committee on Crime in 1997. I am also a frequent presenter at national and international conferences.

6. I have authored and co-authored some over 160 articles in scholarly and professional journals, most of which deal with clinical comparisons of drug therapies. I have contributed chapters of medical textbooks, research publications, clinical protocols and conference reports. My work has been published in the *Journal of Clinical Endocrinology and Metabolism*, *New England Journal of Medicine*, *Journal of the National Cancer Institute*, *Mental Patients in Transition*, *Science Digest*, *Archives of General Psychiatry*, *Comprehensive Psychiatry*, *Clinical Medicine*, *Journal of Psychiatric Research*, *Psychosomatic Medicine*, *Diseases of the Nervous System*, *American Journal of Psychiatry*, *Scientific America*, *Psychopharmacologia*, *International Journal of Psychiatry*, *Encyclopedia of Science and Technology*, *International Narcotic Report*, *New York Law Journal*, *Journal of Consulting and Clinical Psychology*, *Drug Therapy*, *World Journal of Psychosynthesis*, *Medical Tribune*, *Contemporary Drug Problems*, *Social Science and Medicine*, *Villanova Law Review*, *Congressional Digest*, *Biological Psychiatry*, *The Sciences*, *Journal of Ethnopharmacology*, *Handbook on Drug Abuse*, *The Hastings Center Report*, *Harvard Mental*

Health Letter, *Harper's*, *Nova Law Review*, *New Harvard Guide to Psychiatry*, *Journal of State Government*, *Cancer Treatment & Marijuana Therapy*, *Journal of Drug Issues*, *North Carolina Journal of International Law & Commercial Regulation*, *Encyclopedia of Human Biology*, *Drugs, Society and Behavior*, *Journal of American Medical Association*, *University of West Los Angeles Law Review*, and *Journal of Psychoactive Drugs*.

7. I have authored and co-authored some 13 books, several of which deal with the history and medical use of cannabis. These books include *Marihuana Reconsidered* (Harvard University Press, 2d ed. 1977), *Psychedelic Drugs Reconsidered* (Basic Books, 2d ed. 1981), *Psychedelic Reflections* (Human Sciences Press, 1982), *The Long Darkness: Psychological and Moral Perspectives on Nuclear Winter* (Yale University Press, 1986), and *Marihuana, The Forbidden Medicine* (Yale University Press, Revised Edition 1997).

8. Based on my research, I have found that cannabis is remarkably safe. Although not harmless, it is surely less toxic than most of the conventional medicines it could replace if it were legally available. Despite its use by millions of people over thousands of years, cannabis has never caused an overdose death. The most serious concern is respiratory system damage from smoking, but that can easily be addressed by increasing the potency of cannabis and by developing the technology to separate the particulate matter in marijuana smoke from its active ingredients, the cannabinoids (prohibition, incidentally, has prevented this technology from flourishing). Once cannabis regains the place in the U.S. Pharmacopoeia that it lost in 1941 after the passage of the Marihuana Tax Act (1937), it will be among the least toxic substances in that compendium. Right now the greatest danger in using cannabis medically is the illegality that imposes a great deal of anxiety and expense on people who are already suffering.

9. I have done extensive research on the history of the use of cannabis for medical purposes, as well as its legal regulation in the United States. The marijuana, cannabis, or hemp plant is one of the oldest psychoactive plants known to humanity. A native plant of central Asia, cannabis may have been cultivated as much as ten thousand years ago. It was certainly cultivated in China by 4000

B.C. and in Turkestan by 3000 B.C. It has long been used as a medicine in India, China, the Middle East, Southeast Asia, South Africa, and South America. The first evidence of the medicinal use of cannabis was published during the reign of the Chinese Emperor Chen Nun five thousand years ago. Cannabis was recommended for, among other things, malaria and rheumatic pains. Another Chinese herbalist recommended a mixture of hemp, resin, and wine as an analgesic during surgery. Hemp was also noted as a remedy by Galen and other physicians of the classical and Hellenistic eras, and it was highly valued in medieval Europe.

10. Between 1840 and 1900, more than one hundred papers on the therapeutic uses of cannabis were published in American and European medical journals. It was recommended as an appetite stimulant, muscle relaxant, analgesic, sedative, anticonvulsant, and as a treatment for opium addiction. A professor at the Medical College of Calcutta, W.B. O'Shaughnessy, was the first Western physician to observe the use of cannabis as a medicine. He gave cannabis to animals, satisfied himself that it was safe, and began to use it with patients suffering from rabies, rheumatism, epilepsy, and tetanus. In a report published in 1839, he wrote that he had found tincture of hemp (a solution of cannabis in alcohol, taken orally) to be an effective analgesic. He was also impressed with its muscle relaxant properties and called it "an anticonvulsive remedy of the greatest value." In 1890, J.R. Reynolds, a British physician, summarized thirty years of experience with *Cannabis indica*, finding it valuable in the treatment of various forms of neuralgia, including tic douloureux (a painful facial neurological disorder), and added that it was useful in preventing migraine attacks. He also found it useful for certain kinds of epilepsy, for depression, and sometimes for asthma and dysmenorrhea.

11. The medical use of cannabis was in decline by 1890. It was believed that the potency of cannabis preparations was too variable, and that individual responses to orally ingested cannabis seemed erratic and unpredictable. Another reason for the neglect of research on the analgesic properties of cannabis was that the greatly increased use of opiates after the invention of the hypodermic syringe in the 1850s allowed soluble drugs to be injected for faster pain relief; hemp products are

insoluble in water and so cannot easily be administered by injection. Toward the end of the nineteenth century, the development of such synthetic drugs as aspirin, chloral hydrate, and barbiturates, also contributed to the decline of cannabis as a medicine. But these new drugs had, and still have today, striking disadvantages. More than a thousand people die from aspirin-induced bleeding each year in the United States, and barbiturates are, or course, far more dangerous.

12. Cannabis use in the United States was particularly a matter of state or federal regulation until 1915, when the first state, California, prohibited marijuana possession or sale. In 1930, the year in which the Federal Bureau of Narcotics was founded, only sixteen states had laws prohibiting the use of cannabis. In contrast, by 1937, nearly every state had adopted legislation outlawing cannabis. Sociologists have speculated that pressure from the liquor lobby figured among the more subtle factors in this sudden legal onslaught. More important, lack of scientific understanding concerning the effects of cannabis enabled the unsubstantiated statements of the Federal Bureau of Narcotics to go substantially unchallenged. The Marihuana Tax Act of 1937 was the culmination of a series of efforts on the part of the Federal Bureau of Narcotics to generate anti-marijuana legislation.

13. One might have expected physicians looking for better analgesics and hypnotics to turn to cannabinoid substances, but the Marihuana Tax Act of 1937 undermined any such experimentation. The Marihuana Tax Act of 1937 imposed a transfer tax upon certain dealings in marijuana. The Marihuana Tax Act of 1937 provided that anyone who imports, manufactures, produces, compounds, sells, deals in, dispenses, prescribes, administers, or gives away marijuana was required to register, record transactions and pay special taxes depending on the defined purposes. Those who failed to comply were subject to large fines or prison for tax evasion. Although, it was ostensibly designed to prevent nonmedical use of cannabis, the Marihuana Tax Act of 1937 made cannabis so difficult to obtain, that cannabis was removed from the United States Pharmacopoeia and National Formulary in 1941. The Boggs Act of 1951 established

mandatory prison terms and large fines for violation of any federal drug law, and the Narcotic Control Act of 1956 strengthened those penalties.

14. In the 1960s, however, the public began to rediscover the medical value of cannabis, as letters appeared in lay publications from people who had learned that it could relieve their asthma, nausea, muscle spasms, or pain and wanted to share that knowledge with readers who were familiar with the drug. Meanwhile, legislative concern about recreational use of cannabis increased, and in 1970 Congress passed the Comprehensive Drug Abuse Prevention and Control Act (also called the Controlled Substances Act), which assigned psychoactive drugs to five schedules and placed cannabis in Schedule I, the most restrictive.

15. A few patients have been able to obtain medical cannabis legally in the last twenty years. Beginning in the 1970s, thirty-five states passed legislation that would have permitted medical use of cannabis but for the federal law. Several of those states actually established special research programs, with the permission of the federal government, under which patients who were receiving cancer chemotherapy would be allowed to use cannabis. These projects demonstrated the value of both smoked marijuana and oral THC (tetrahydrocannabinol). The FDA approved oral THC (Marinol) as a prescription medicine in 1986. In 1976, the federal government introduced the Individual Treatment Investigational New Drug program (commonly referred to as the Compassionate IND), which provided cannabis to a few patients whose doctors were willing to undergo the paperwork-burdened and time-consuming application process. About three dozen patients eventually received cannabis before the program was discontinued in 1992, and seven survivors are still receiving it — the only persons in the country for whom it is not a forbidden medicine.

16. The most effective spur to the movement for medical marijuana came from the discovery that it could prevent the AIDS wasting syndrome. It is not surprising that the Physicians Association for AIDS Care was one of the medical organizations that endorsed the California initiative prohibiting criminal prosecution of medical marijuana users.

17. I have conducted an extensive review of the literature concerning medical uses of cannabis and I am familiar with studies on the topic. Review of medical literature is a commonly used research tool. I have also studied clinically many patients who have used cannabis for the relief of a variety of symptoms; this clinical experience forms the basis of my book, *Marihuana, The Forbidden Medicine.* In my book I provide first-person accounts of the ways that cannabis alleviates symptoms of cancer chemotherapy, multiple sclerosis, osteoarthritis, glaucoma, AIDS and depressions, as well as symptoms of such less common disorders as Crohn's disease, diabetic gastroparesis, and post-traumatic stress disorder. The patient narratives illustrate not only cannabis's therapeutic properties but also the unnecessary further pain and anxiety imposed on sick people who must obtain cannabis illegally.

18. Cannabis has several uses in the treatment of cancer. As an appetite stimulant, it can help to slow weight loss in cancer patients. It may also act as a mood elevator. But the most common use is the prevention of nausea and vomiting associated with cancer chemotherapy. About half of patients treated with anticancer drugs suffer from severe nausea and vomiting, which are not only unpleasant and painful but a threat to the effectiveness of the therapy. Retching can cause tears of the esophagus and rib fractures, prevent adequate nutrition, and lead to fluid loss. Some patients find the nausea so intolerable they say they would rather die than go on. The antiemetics most commonly used in chemotherapy are metoclopramide (Reglan), the relatively new ondansetron (Zofran), and the newer granisetron (Kytril). Unfortunately, for many cancer patients these conventional antiemetics do not work at all or provide little relief.

19. The suggestion that cannabis might be used in the treatment of cancer arose in the early 1970s when some young patients receiving cancer chemotherapy found that marijuana smoking reduced their nausea and vomiting. In one study of 56 patients who got no relief from standard antiemetic agents, 78% became symptom-free when they smoked marijuana.[1] Oral tetrahydrocannabinol

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[1] Vinciguerra, V., et al. Inhalation Marihuana as an antiemetic for cancer chemotherapy. *New York State Journal of Medicine* 1988; 88:525-527. (Attached as Exhibit B).

(THC) has proved effective where the standard drugs were not,[2] but smoking generates faster and more predictable results because it raises THC concentration in the blood more easily to the needed level. Also, it may be hard for a nauseated patient to take oral medicine. In fact, there is strong evidence that most patients suffering from nausea and vomiting prefer smoked marijuana to oral THC.

20. Oncologists may be ahead of other physicians in recognizing the therapeutic potential of cannabis. In the spring of 1990, two investigators randomly selected more than 2,000 members of the American Society of Clinical Oncology (one-third of the membership and mailed them an anonymous questionnaire to learn their views on the use of cannabis in cancer chemotherapy. Almost half of the recipients responded. Although the investigators acknowledged that this group was self-selected and that there might be a response bias, their results provide a rough estimate of the views of specialists on the use of Marinol (dronabinol, oral synthetic THC) and smoked marijuana. Only 43% said the available legal antiemetic drugs (including Marinol) provided adequate relief to all or most of their patients, and only 46% said the side effects of these drugs were rarely a serious problem. Forty-four percent had recommended the illegal use of cannabis to at least one patient, and half would prescribe it to some patients if it were legal. On average, they considered smoked marijuana more effective than Marinol and roughly as safe.[3]

21. Cannabis is also useful in the treatment of glaucoma, the second leading cause of blindness in the United States. In this disease, fluid pressure within the eyeball increases until it damages the optic nerve. About a million Americans suffer from the form of glaucoma (open angle) treatable with cannabis. Glaucoma is treated chiefly with eyedrops containing betablockers such as timolol (Timoptic), which inhibit the activity of epinephrine (adrenaline). They are effective but may

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[2] Sallan, S.E., et al. Antiemetic effect of delta-9-tetrahydrocannabinol in patients receiving cancer chemotherapy. *New England Journal of Medicine* 1975; 293:795-797. (Attached as Exhibit C).

[3] Doblin R. Kleiman M. Marihuana as anti-emetic medicine: a survey of oncologists' attitudes and experiences. *Journal of Clinical Oncology* 1991; 9:1275-80. (Attached as Exhibit D).

have serious side effects such as inducing depression, aggravating asthma, slowing the heart rate, and increasing the risk of heart failure. Cannabis causes a dose-related, clinically significant drop in intraocular pressure that lasts several hours in both normal subjects and those with the abnormally high ocular tension produced by glaucoma. Oral or intravenous THC has the same effect, which seems to be specific to cannabis derivatives rather than simply a result of sedation. Cannabis does not cure the disease, but it can retard the progressive loss of sight when conventional medication fails and surgery is too dangerous.[4]

22. About 20% of epileptic patients do not get much relief from conventional anticonvulsant medications. Cannabis has been explored as an alternative at least since 1975 when a case was reported in which marijuana smoking, together with the standard anticonvulsants Phenobarbital and diphenylhydantoin, was apparently necessary to control seizures in a young epileptic man.[5] The cannabis derivative that is most promising as an anticonvulsant is cannabidiol. In one controlled study, cannabidiol in addition to prescribed anticonvulsants produced improvement in seven patients with grand mal convulsions; three showed great improvement. Of eight patients who received a placebo instead, only one improved.[6] There are patients suffering from both grand mal and partial seizure disorders who find that smoked marijuana allows them to lower the doses of conventional anticonvulsant medications or dispense with them altogether. Furthermore, anticonvulsants have many potentially serious side effects, including bone softening, anemia, swelling of the gums, double vision, hair loss, headaches, nausea, decreased libido, impotence, depression, and psychosis. Overdoses or idiosyncratic reactions may lead to loss of motor coordination, coma or even death.

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[4] Hepler, R.S., et al. Ocular Effects of Marihuana Smoking. M.C. Braude, S. Szara (eds.). *The Pharmacology of Marihuana*. New York: Raven Press, 1976.

[5] Consroe, Paul F., et al. Anticonvulsant nature of Marihuana smoking. *Journal of the American Medical Association* 1975; 234-306-307. (Attached as Exhibit E).

[6] Cunha, J.M., et al. Chronic administration of cannabidiol to healthy volunteers and epileptic patients. *Pharmacology* 1980; 21:175-185. (Attached as Exhibit F).

23. There are many case reports of cannabis smokers using the drug to reduce pain: post-surgery pain, headache, migraine, menstrual cramps, and so on. Ironically, the best alternative analgesics are the potentially addictive and lethal opioids. In particular, cannabis is becoming increasingly recognized as the most effective treatment for the pain that accompanies muscle spasm, which is often chronic and debilitating, especially in paraplegics, quadriplegics, other victims of traumatic nerve injury, and people suffering from multiple sclerosis or cerebral palsy. Many of them have discovered that cannabis not only allows them to avoid the risks of other drugs, but also reduces muscle spasms and tremors; sometimes they are even able to leave their wheelchairs.[7]

24. One of the most common causes of chronic pain is osteoarthritis, which is usually treated with synthetic analgesics. The most widely used of these drugs — aspirin, acetaminophen (Tylenol), and nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen and naproxen — are not addictive, but they are often insufficiently powerful. Furthermore, they have serious side effects. Stomach bleeding and ulcer induced by aspirin and NSAIDs are the most common serious adverse drug reactions reported in the United States, causing an estimated 7,000 deaths each year. Acetaminophen can cause liver damage or kidney failure when used regularly for long periods of time; a recent study suggests it may account for 10% of all cases of end-stage renal disease, a condition that requires dialysis or a kidney transplant.[8] Cannabis, as I pointed out earlier, has never been shown to cause death or serious illness. The University of Iowa conducted a study of cannabis for the relief of pain. Researchers gave oral THC or placebo at random to hospitalized cancer patients who were in severe pain. The THC relieved pain for several hours in doses as low

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[7] Petro, D. J., Ellenberger, C., Treatment of human spasticity with delta-9-tetrahydrocannabinol. *Journal of Clinical Pharmacology* 1981; 21:413-416. (Attached as Exhibit G).

[8] Perneger, T.V., Whelton, P., Klag, M.J. Risk of kidney failure associated with the use of acetaminophen, aspirin, and nonsteroidal anti-inflammatory drugs. *New England Journal of Medicine* 1994; 331:25:1675-1679. (Attached as Exhibit H).

as 5-10 mg, and for even longer at 20 mg. At this dose and in this setting, THC proved to be a sedative as well. It had few physical side effects than other commonly used analgesics.[9]

25. Oncologists are legally permitted to administer the synthetic THC (Marinol) orally in capsule form. But inhaled cannabis may be necessary for several reasons. For one thing, oral THC is subject to the variances of bioavailability. This means that two patients who take the same amount may absorb different proportions of the dose, and a given patient may respond differently on different days, depending on the condition of the intestinal tract and other factors. Furthermore, the effects of smoked cannabis are perceived almost immediately, so patients can smoke slowly and take only what they need for a therapeutic effect. Patients who swallow Marinol may discover after an hour or so that they have taken too much for comfort or not enough to relieve their symptoms. In any case, a patient who is severely nauseated and constantly vomiting may find it almost impossible to the capsule down. Furthermore, Marinol makes some patients anxious and uncomfortable. Smoked cannabis, unlike Marinol, contains other substances which reduces anxiety caused by the THC.

26. In theory, all the therapeutic properties of cannabis could be used if individual cannabinoids in addition to THC were isolated and made available separately as medicines. But this would be an enormously complicated procedure. Research sponsors would have to determine the therapeutic potential and evaluate the safety of sixty or more substances, synthesize each one found to be useful, and package it as a pill or aerosol. As some of these substances probably act synergistically, it would also be necessary to look at various combinations of them. However no drug company would provide the resources needed for such a project because cannabis can not be patented, it is a plant material containing many chemicals rather than a single one and no drug in the present pharmacopoeia is delivered by smoking.

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[9] R. Noyes, S. F. Brunk, D. A. Baram, and A. Canter, "Analgesic Effect of Delta-9-tetrahydrocannabinol," *Journal of Clinical Pharmacology* 15 (February-March 1975): 139-143. (Attached as Exhibit I).

27. More than 300,000 Americans have died of AIDS. Nearly a million are infected with HIV, and at least a quarter of a million have AIDS. Although the spread of AIDS has slowed among homosexual men, the reservoir is so huge that the number of cases is sure to grow. Women and children as well as both heterosexual and homosexual men are now being affected; the disease is spreading most rapidly among intravenous drug abusers and their sexual partners. The disease can be attacked with anti-viral drugs, of which the best known are zidovudine (AZT) and protease inhibitors. Unfortunately, these drugs sometimes cause severe nausea that heightens the danger of semi-starvation for patients who are already suffering from nausea and losing weight because of the illness — a condition sometimes called the AIDS wasting syndrome.

28. Cannabis is particularly useful for patients who suffer from AIDS because it not only relieves the nausea but also retards weight loss by enhancing appetite. In one study the body weight and caloric intake of twenty-seven marijuana users and ten control subjects were compared for twenty-one days on a hospital research ward. The marijuana smokers ate more than the controls and gained weight; the controls did not. When they stopped smoking marijuana, they immediately started to eat less.[10] When it helps patients regain lost weight, it can prolong life. Although Marinol has been shown to relieve nausea and retard or reverse weight loss in patients with HIV infection, most patients prefer smoked cannabis for the same reasons that cancer chemotherapy patients prefer smoked cannabis. Cannabis is more effective and has fewer unpleasant side effects, and the dosage is easier to adjust. Many patients report that cannabis provides an appetite and pain relief without the semi-comatose effect of narcotics.

29. Opponents of medical cannabis often object that the evidence of its usefulness, although strong, comes only from case reports and clinical experience. It is true that there are no double-blind controlled studies meeting the standards of the Food and Drug Administration, chiefly because legal, bureaucratic, and financial obstacles have been constantly put in the way. However, we

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[10] I. Greenberg, J. Kuehnle, J. H. Mendelson, and J. G. Bernstein, "Effects of Marijuana Use of Body Weight and Caloric Intake in Humans," *Journal of Psychopharmacology* (Berlin) 49 (1976): 79-84. (Attached as Exhibit J).

know more about cannabis than about most prescription drugs. Furthermore, individual therapeutic responses are often obscured in group experiments, and case reports and clinical experience are the source of much of our knowledge of drugs. As Dr. Louis Lasagna has pointed out, controlled experiments were not needed to recognize the therapeutic potential of chloral hydrate, barbiturates, aspirin, insulin, or penicillin.[11] Nor was that the way we learned about the use of propranolol for hypertension, diazepam for status epilepticus, and imipramine for enuresis. All these drugs had originally been approved for other purposes.

30. In the experimental method known as the single patient randomized trial, active and placebo treatments are administered randomly in alternation or succession. The method is often used when large-scale controlled studies are inappropriate because the disorder is rare, the patient is atypical, or the response to treatment is idiosyncratic.[12] Several patients have told me that they assured themselves of cannabis's effectiveness by carrying out such experiments on themselves, alternating periods of cannabis use with periods of abstention. I am convinced that the medical reputation of cannabis is derived partly from similar experiments conducted by many other patients.

31. Some physicians may regard it as irresponsible to advocate use of a medicine on the basis of case reports, which are sometimes disparaged as merely "anecdotal" evidence which counts apparent successes and ignores apparent failures. That would be a serious problem only if cannabis were a dangerous drug. The years of effort devoted to showing that cannabis is exceedingly dangerous have proved the opposite. It is safer, with fewer serious side effects, than most prescription

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[11] Lasagne, L. Clinical trials in the natural environment. C. Stiechele, W. Abshagan, J. Kich-Weser (eds.). *In Drugs Between Research and Regulations*. New York: Springer-Verlag, 1985: 45-49. (Attached as Exhibit K).

[12] Larson, E.B. N-of-1 clinical trials: A technique for improving medical therapeutics. *Western Journal of Medicine* 1990; 152:52-56; Guyatt, G.H., Keller, J.L., Jaeschke, R., et al. The N-of-1 randomized controlled trial: Clinical usefulness. *Annals of Internal Medicine* 1990; 112:293-299. (Attached as Exhibit L).

medicines, and far less addictive or subject to abuse than many drugs now used as muscle relaxants, hypnotics, and analgesics.

32. Based on the best available medical information, it is evident that cannabis should be made available even if only a few patients could get relief from it, because the risks are so small. For example, as I mentioned, many patients with multiple sclerosis find that cannabis reduces their muscle spasma and pain. A physician may not be sure that such a patient will get more relief from cannabis than from the standard drugs baclofen, dantrolene, and diazepam — all of which are potentially dangerous or addictive — but it is almost certain that a serious toxic reaction to cannabis will not occur. Therefore the potential benefit is much greater than any potential risk.

33. During the past few years, the medical uses of cannabis have become increasingly clear to many physicians and patients, and the number of people with direct experience of these uses has been growing. Therefore, the discussion is now turning from whether cannabis is an effective medicine to how it should be made available.

34. The government's position that cannabis has no accepted medical use is not rational, given the wealth of information confirming that cannabis is an effective medicine. Moreover, in my view, the government has long obstructed efforts to conduct research concerning cannabis. Had the United States government not stood in the way of such research, I believe that we would be at least 50 years ahead of where we are today in making cannabis available to persons who need it for medical reasons.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 5 day of March, 2002, at Wellesley, Massachusetts.

Lester Grinspoon MD

LESTER GRINSPOON, M.D.